APR 2 4 2001

K010225

Dosimetry Check System
File: dcsm510k.doc
Date: Nov. 20, 2000

510(k) Summary

Dosimetry Check is a software program intended to provide a means for testing the dosimetry of radiation therapy treatment applied to a patient using high energy x-rays. This test is performed from measurements make independently of the patient. Information is gathered in a treatment run without the patient and consist of making a calibrated image of each of the radiation fields that is to be applied to the patient. However, if suitable technology and measurement systems exist, images of the treatment field could be used that might have been made during treatment. The following software functions are then performed:

1. Read in an image of each radiation field, in DICOM or other suitable image format.
2. If suitable technology exist, to read in images of fields that changed during gantry rotation, such images tagged to the gantry angle at the time of measurement.
3. Provide means of generating a calibration curve to convert pixel value to relative monitor units or to centiGray.
4. Provide means of using the calibration curve to calibrate a step wedge.
5. Provide means to use the calibrated step wedge to generate a calibration curve.
6. Provide means to use the calibration curve to convert the field image to a field calibrated in relative monitor units or centiGray. However, for this application relative monitor units are required.
7. Provide means to renormalized the field image at a specific point where a separate measurement was made, either with an ion chamber, diode, or other suitable dosimeter. Included here is the ability to make a temperature pressure correction for ion chambers and to assign a calibration constant to the dosimeter for conversion of signal to dose or relative monitor units.
8. Provide means to align the field image with the beam's eye view coordinate system of the radiation machine, and to correct for any tilt, offset, or image flipping, and to determine the source image distance if need be.
9. Provide means to make a hard copy of the measured radiation field with isodose lines in either cGray, relative monitor units, or relative percent.
10. Provide means to read in the CT scans and other image modalities used in the treatment planning process.
11. Provide means to define a skin boundary from the image set that represents the patient.
12. Provide a means for the conversion of CT number to density in cg/milliliter or electron density relative to water.
13. Provide means to define and locate on the image of each radiation field the center ray of the radiation field, and to specify the energy, and gantry, collimator, and couch angles of such beams. Further, to define the gantry start and stopping angles for arc therapy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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APR 2 4 2001

Mr. Wendel Dean Renner
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Re: K010225
Dosimetry Check Version 1, Release 1
Dated: January 23, 2001
Received: January 24, 2001
Regulatory Class: II
21 CFR §892.5050/Procode: 90 IYE

Dear Mr. Renner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

File: dcinduse.doc
Date: Nov. 20. 2000
Date: Apr. 23, 2001

510(k) Number: K010225
Device Name: Dosimetry Check
Indications for Use:

The product is to be used by radiation oncologist, dosimetrist, and radiation therapy physicist to check the correctness of the x-ray treatment fields from high energy treatment machines that are planned to be or have been applied to a patient. This product is to be used in addition to the treatment planning system to provide a means for additional and redundant verification that the plan is in fact successfully accomplished. This product is not a treatment planning system and is not to be used as one. This product only checks the applied dose based on the measurement of each x-ray field and a theoretical calculation. This product does not provide any quality assurance that the fields are in fact correctly applied to and correctly aligned with the patient anatomy as planned. In addition, the product may be used to display the above dose on other fused image sets which could provide additional clinical information to the radiation oncologist regarding the treatment.

Document approved by: Wendel Dean Renner Wendel Dean Renner
Title: President Date: April 23, 2001

Prescription Use ✓

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010225